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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,549	10/10/2003	Fabian Somers	DI-5954 (BXTD 9004.6)	2624

321 7590 06/13/2006

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/683,549	Applicant(s) SOMERS ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: None.
 Claim(s) objected to: None.
 Claim(s) rejected: 16,20-22,24-31,33-35 and 37.
 Claim(s) withdrawn from consideration: 18 and 38-40.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
 13. ☐ Other: _____.

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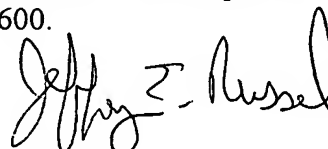
1. There is support under 35 U.S.C. 112, first paragraph, for the proposed amendments to the claims. However, the proposed language with respect to alpha-keto forms, or with respect to derivatives which include nitro Phe, cyclohexyl Ala, or p-amino Phe, raise new issues under 35 U.S.C. 112, second paragraph. With respect to the alpha-keto forms, the examiner agrees that the Stryer text, attached to Applicants' response, adequately teaches the structure of alpha-keto amino acids. Given the structure of the alpha-keto forms taught by the Stryer text, it appears that only a N-terminal amino acid of one of the recited peptide stabilizers can be replaced with an alpha-keto amino acid because no valence on the alpha carbon of an alpha-keto amino acid is available for peptide bond formation. However, Applicants summarize in their remarks at page 5, third paragraph, that "alpha-keto forms of the claimed peptide stabilizers have an alpha-amino substituent which has been replaced by a keto substituent on the alpha carbon of at least one of the amino acids in the dipeptide or tripeptide", which indicates that replacement can occur at other than the N-terminus of a peptide stabilizer. The structure of such derivatives is therefore unclear. With respect to the derivatives which include nitro Phe, cyclohexyl Ala, or p-amino Phe, it is not clear if the proposed claim language should be interpreted as permitting any one or all of the amino acids in the recited peptide stabilizers to be replaced with nitro Phe, cyclohexyl Ala, or p-amino Phe; as permitting the insertion of any number of nitro Phe, cyclohexyl Ala, or p-amino Phe residues into the recited peptide stabilizers; or as permitting only the most structurally closely related amino acids in the recited peptide stabilizers, i.e. the Tyr or Phe residues, to be replaced by the nitro Phe, cyclohexyl Ala, or p-amino Phe residues.
2. The proposed derivative language would have overcome the prior art rejections based upon Sato et al and the WO Patent Application '241 as the primary references.

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3. The proposed amendments changing the product claims into method claims where the composition is parenterally administered would not have overcome the prior art rejections based upon Cormier et al as the primary reference. Cormier et al teach transdermal administration, which is a species of parenteral administration. (Note that "parenteral" is defined as "by some other means than through the gastrointestinal tract".) As discussed in the interview on April 6, 2006, it is a method of parenteral "injection" which would distinguish over Cormier et al. While Applicants' remarks often refer to parenteral injection as opposed to parenteral administration (see, e.g., page 11, first paragraph), the injection language is not found in the proposed claim amendments.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
June 9, 2006